REMARKS

Claims 1-3, 5-10, 12-17, 19-29, 31-39, and 41-46 were previously pending in the present Application. Claims 1-3, 5-10, 12-17, 19-29, and 31-36 have been cancelled without prejudice by the above amendment. Claims 37-39 and 41-46 have been amended. New claims 47-64 have been added. Claims 37-39 and 41-64, therefore, are present for consideration upon entry of the present Amendment.

Claim 37 has been amended to more clearly place the term "amorphous" nearer the "silica" it modifies, as supported by the original claim. Claim 37 has been further amended to recite heating at at about or above about 800°C, as supported, as supported at least at page 12, lines 4-5. Dependent claims 38-39 and 41-46 have been amended by deleting the word "silica" in the preamble for consistency with independent claim 37.

Amendments to and additions to the claims, as set forth above, are made in order to streamline prosecution in this case by limiting examination and argument to certain claimed embodiments that presently are considered to be of immediate commercial significance. Amendment of the claims is not in any manner intended to, and should not be construed to, waive Applicants' right in the future to seek such unamended subject matter, or similar matter (whether in equivalent, broader, or narrower form) in the present application, and any continuation, divisional, continuation-in-part, RCE, or any other application claiming priority to or through the present application, nor in any manner to indicate an intention, expressed or implied, to surrender any equivalent to the claims as pending after such amendments.

Briefly, to recap, the present invention relates to a novel filler for use in dental composites in which the filler is prepared by drying a sol comprising elongated amorphous silica nanoparticles, which have diameters of about 1 to about 50 nanometers, wherein the nanoparticles are in the form of chains of colloidal particles bound to each other and have lengths of about 5 to about 400 nanometers. The dried silica sol is heated to a temperature and for a time effective to form at least one crystalline phase therein. Without wishing to be bound by theory, it is hypothesized that the "strings" or "pearls" of bound silica improve fracture resistance compared to discrete particular materials. In one embodiment of the claimed invention, the filler is a hybrid comprising nanoparticulate silica that is fused onto the surfaces of a microparticulate filler. Dental composites containing the novel filler of the invention can exhibit superior wear resistance, as demonstrated in Table 5, on page 23 of the present specification.

Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

Obviousness over Zhang

Claims 37-39 and 41-43 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,387,981 to Zhang et al. (hereafter "Zhang"). Applicants respectfully traverse this rejection.

The Office Action states:

> Zhang teaches a dental material having silica particles less than 100 nm (Col. 5) which is surface treated with a silane (Col. 6, lines 1-19) and which may have additional ceramic filler (Col. 7, lines 4-10) as well as opacifying oxides (Col. 6, line 38 to Col. 7, line 3) wherein the silica comprises fumed silica (col. 5).

As Applicants pointed out in the response of November 24, 2008, Zhang fails to teach (1) drying a sol comprising individual silica nanoparticles in the form of chains having lengths of about 5 to about 400 nanometers; and (2) heating the dried silica sol to a temperature and for a time effective to form at least one crystalline phase within the resulting silica material. Each of these two aspects of the presently claimed invention will be discussed in turn.

First, nowhere does Zhang remotely teach individual silica nanoparticles of a sol in the form of chains having lengths of about 5 to about 400 nanometers, which clearly means that the nanoparticles are individually colloidally dispersed. Thus, an important difference between Zhang and the presently claimed invention is the presence, in a sol used to make the filler, of colloidally dispersed individual particles of an elongated silica nanoparticles comprising a chain of particles bound to each other. This differs from both spherical nanopartices and fumed silica as the starting material.

Applicants respectfully submit that Zhang is generally directed to a dental material comprising a hardenable resin, a non-heavy metal oxide particle and a heavy metal oxide, wherein the non-heavy metal oxide particles can be silica particles, particularly fumed silica, colloidal silica, or aggregated silica particles. (Zhang, Abstract and column 5, lines 17-67.) It appears to be the position of the Examiner that the fumed silica in Zhang inherently is formed into chains. This is not stated in the Office Action of 12/09/2008, and Zhang makes no mention of such chains. However, in the Office Action of 10/31/2007, the Examiner cited U.S. Patent No. 6,193,792 to Fague, specifically column 7, lines 47-50, for stating that fumed silica contain chains of bound silica particles. Disregarding the fact that Fague was not cited in the present rejection, Fague only stated that fumed silica "consists" of chains, not that individual particles in the form of such chains are dispersed in a sol.

Drawing a distinction between fumed silica and what is commonly referred to as "colloidal silica" may be helpful. Colloidal silica can be produced by a wet process such as precipitation, whereas fumed silica is produced in a gas phase reaction. Colloidal silica is typically formed as individually dispersed ("monodispersed") particles, whereas fumed silica typically forms "agglomerates," that is, secondary particles made up of smaller primary particles. Fague is apparently referring to the primary particles of fumed silica in the form of chains, which are typically present in the form of agglomerates or secondary particles. Such secondary particles can be colloidally dispersed, but colloidal dispersions of fumed silica are not normally referred to as colloidal silica, as indicated in the above quote by Zhang. Most usually, colloidal silica comprises substantially monodispersed substantially spherical particles. Thus, the NALCO or LUDOX colloidal silica products in the Examples of Zhang are generally non-aggregated (i.e., individually dispersed particles) in the form of spherical silica particles dispersed in an aqueous or organic media. In the present invention, however, the colloidal particles have a unique elongated chain form, which are individually dispersed as in a sol.

Thus, it is respectfully submitted that the Examiner is under a misunderstanding with respect to the present invention. The invention is based, not on fumed silica particles, which typically consist of secondary particles comprised of primary particles, but on "colloidal silica." This distinction is also discussed in Fague, column 7, lines 47-50. Fague refers to "precipitated colloidal silica" in distinction to fumed silica. Similarly, Zhang similarly refers to "colloidal silica." Zhang states:

> Preferably, the non-metallic oxide particles are silica that are present in the dental material in various forms, including for example, fumed silica, colloidal silica, or aggregated silica particles. As used herein, "colloidal" means discrete (individual) and unassociated (i.e., non-aggregated and non-agglomerated). "Agglomerated" as used herein, is descriptive of a weak association of particles usually held together by charge or polarity and can be broken down into smaller entities." "Aggregated," as used herein, is descriptive of a strong association of particles often bound together by, for example, residual chemicals treatment; further breakdown of the aggregates into smaller entities is very difficult to achieve. [Col. 5, lines 17-33.]

The distinction between "aggregates" and "agglomerates" seems sometimes unclear or variable in the art, so a better distinction may be between primary particles and secondary particles. Fumed silica typically comprises secondary particles formed by weak van de Waals forces.

Zhang further states, "The silica used in the materials of the present invention are preferably substantially spherical and substantially non-porous...Preferred silicas for use in the materials of the present invention are ....NALCO COLLOIDAL SILICAS." [col. 5, lines 58-61.] The suitable fumed silicas taught by Zhang include AEROSIL and CAB-O-SIL. These products are secondary particles made up of primary particles, as indicated by Wiki (sheet attached), in which AEROSIL silica is described as aggregated nano-sized primary particles. Similarly a conventional definition of CAB-O-SIL is a low density and high surface area silica, indicative of secondary particles.

In view of the distinctions between colloidal silica and fumed silica, Applicants respectfully submit that claim 37 is directed to a filler made from a sol comprising amorphous silica nanoparticles wherein the individual nanoparticles of the sol are in the form of chains [emphasis added], which is nowhere taught by Zhang. In particular, Zhang's disclosure of fumed silica teaches away from the presently claimed invention.

The Office Action, after asserting that the fumed silica in Zhang teaches the present invention, then refers to non-fumed colloidal silica in the form of clusters. 12/09/09 Office Action page 3, first paragraph. In particular, the Office Action states:

> Zhang teaches a method of heating a silicic sol in accordance with the invention, which includes heating a silica sol at a temperature of 600°C (col. 14, lines 57-60), heating step as taught in 09/428,830 (page 30, lines 10-15 of specification) incorporated into Zhang by reference, col. 15, lines 1-5, the clusters are made up of silica sols). 12/09/09 Office Action page 2, last paragraph.

Since these clusters do not comprise fumed silica, it will be assumed that the Office Action considers this to be an alternative teaching to the fumed silica in Zhang. Apparently, the theory of this part of the rejection is that clusters of particles are the same as, or somehow contain, nanoparticles in the form of chains. The Office Action later states:

> Additionally, one of ordinary skill in the art would recognize that in forming clusters, chains would inherently be formed in the cluster making process (Fig. 1).

This does not support the rejection for two reasons. First, each cluster is not an individual nanoparticle, but rather is made up from an "association" or "clump" of discrete individual nanoparticles. (Col. 14, lines 21-23.) The cluster is not an individual nanoparticle. It is described as having an average diameter of less than about 5 micrometers. Zhang states as follows:

> Typically the non-heavy metal oxide particles [emphasis on plurality added] of the clusters are associated by relatively weak intermolecular forces that cause the non-heavy metal oxide particles to clump together, even when dispersed in a hardenable resin for a dental material....To the extent that the heavy metal oxide is present in the cluster as particles, the heavy metal oxide particles display a similar association to each other and to the non-heavy metal oxide particles." [Column 14, lines 24-31.]

Zhang cites U.S. Patent Application Serial No. 09/428,830, now U.S. Patent No. 6,730,156 to Windisch, hereafter "Windisch") for the process of making the clusters. Windisch states that, "The resulting fillers are weakly bound aggregates or clusters of discrete primary particles which are clustered together…." (Column 20, lines 14-19, of Windisch.)

Furthermore, the clusters are not dispersed in a sol, but rather prepared from a sol, only after removing liquid from the sol to form a solid material. Since the clusters of Zhang/Windisch do not exist in the sol, such clusters cannot be compared to the present elongated nanoparticles in the form of chains. The clusters are formed only after the sol of Zhang/Windisch is dried. Windisch states:

> The clusters are prepared from a suitable sol… For purposes of this invention, a sol is defined as a stable dispersion of colloidal solid particles…the sol should be free of impurities that cause undue aggregation (during the filler preparation process) of the individual discrete particles, during the subsequent steps….

In other words, the filler clusters of Zhang are really the result of drying and heating a sol of individual spherical nanoparticles. This is further illustrated by the cluster image (Fig. 1) in Zhang, which is an image of the invented dental material (col. 2, lines 59-62, and Brief description of the drawing). This materials contains a hardenable resin in addition to the nanofiller of non-heavy metal oxide and heavy metal oxide. This is not an image of the nanoparticles as they would appear in a sol. According to Zhang, the method of determining the average particle diameter applies to a cured dental material approximately 80 nm thick under TEM observation (col. 5, lines 44 – 52; Col. 28, lines 31 – 38). Thus, the cluster in the image of Fig. 1 is from a composite, i.e., from a dried and heated filler material within a resin. These clusters are not analogous to the chains of the present sol, but rather are produced from monodispersed spherical particles of a sol. The spherical particles (about 50 nm in diameter) in the sol of Zhang/Windisch are later clustered. Moreover, it would appear from Fig. 1 that the size of the clusters mentioned in Zhang are greater than the size of the chains in the present claims. Windisch states that the clusters are less than about 5 microns, preferably less than 2 microns, which is 2000 nanometers. In the Examples of Windisch, the average cluster size is 1 micron, i.e., 1000 nanometers. (Windisch at col. 25, line 62.)

Thus, the elongated silica chains used to make the presently claimed filler is not a "cluster" formed through a drying or heating process and not formed from monodispersed spherical silica, but a colloidal silica in a sol having special elongated features.

The Office Action also states that one of ordinary skill would recognize an optimum size of a cluster, and it would be obvious to one of ordinary skill in the art to optimize the size of the clusters. (12/09/2008 Office Action page 3, para. 3 and 4.) Applicants submit, however, as discussed above, that the optimum size of the clusters or optimizing the filler clusters in Zhang/Windisch is not relevant to the size of the individual nanoparticulate particles of the sol used to make the presently claimed filler.

In contrast to either Zhang's clusters, fumed silica, or spherical monodispersed colloidal silica, the elongated silica nanoparticles used to make the presently claimed fillers are the kind of colloidal silica disclosed in U.S. Patent No. 5,221, 497 to Watanabe et al. (hereafter "Watanabe"). Watanabe, for example, discloses one method of making elongated silica nanoparticles involving mixing a small amount of water-soluble calcium and magnesium salts with silicic acid, among other features of a complex process. (Watanabe, Abstract.) The result is that "part of the active silicic particles, which have captured the calcium ions and/or magnesium ions therewith, would be chain-like coagulated in trying in a row thereby forming string-like elongated coagulated particles which may be angled in any direction." (Watanabe, column 7, lines 24-29.) Such particles are shown in Fig. 1 of Watanabe.

Second, the present invention is distinguished from Zhang by requiring a filler obtained by heating the dried silica sol to a temperature and for a time effective to form at least one crystalline phase within the resulting silica material. In particular, a further distinction of the present invention is that the colloidal silica particles, initially amorphous in the sol, are treated to obtain crystal structure. In contrast, fumed particles are amorphous, as has been shown by X-ray diffraction measurement. There is no teaching in Zhang to heat a fumed-silica material or its effect on crystallinity. Only after heating at very high temperatures do the present elongated nanoparticles form a crystalline phase.

In fact, it should also be noted that Zhang fails to teach heating any dried amorphous silica sol to a temperature and for a time effective to form at least one crystalline phase within the resulting silica material. Although the Office Action cites heating in Zhang (Col. 14, lines 57-60) with respect to the above-discussed clusters, the stated result of such heat treatment is a substantially amorphous cluster that is essentially free of crystalline structure. (Zhang, column 14, lines 10-13 and 32-42.)

In particular, Zhang discloses in columns 14, line 10, to column 15, line 42, that the clusters are "substantially amorphous," which is defined to mean that "the clusters are essentially free of crystalline structure…." Zhang further states that the fillers of the invention "preferably have an index of less than about 0.1; more preferably less than about 0.05" on the Crystallinity Index where 1.0 is indicative of a full crystalline structure and "a value near zero indicates presence of amorphous phase only." (Zhang, Col. 14, lines 32-42.)

Furthermore, although Zhang teaches a heat treatment, there is not only no teaching that any crystallinity is produced by that heat treatment, since the resulting clusters are described as essentially free of crystalline structure, but rather there is a positive teaching that crystallinity is to be avoided. In particular, Zhang refers, as noted by the Examiner, to the above-mentioned U.S. Patent Application Serial No. 09/428,830 (U.S. Patent No. 6,730,156 to Windisch et al.) as teaching, with respect to the clusters, calcining at a temperature of 200°C to 800°C, more preferably about 300 to 600°C, in order "to further remove residual organics. " Windisch further states that this calcining "allows the filler to become more brittle, which results in more efficient particle size reduction." (Column 19, lines 56-61, of Windisch.) Of particular relevance to the present discussion, Windisch states:

> The provision of substantially amorphous clusters may be facilitated by the appropriate selection of heat treatments, for example, by maintaining the temperature of a heat treatment at a level that is sufficiently low that essentially no crystallinity is found after milling." (Column 18, lines 62-67.)

Thus, even with the combined teaching of Zhang and U.S. Patent Application Serial No. 09/428,830, the heat treatment disclosed in Zhang produces, starting with monodispersed spherical colloidal particles, a dried material that is a "substantially amorphous" cluster of non-heavy metal oxide and a heavy metal oxide and does not produce, starting from a sol comprising individual particles of elongated silica in the form of chains, a material having a crystalline phase according to the instant claims.

In distinct contrast to the teachings of Zhang/Windisch, the elongated silica nanoparticles used in making the present filler (for example, as Snowtex PS-M colloidal silica, commercially available for Nissan Chemical Company) obtain a crystalline phase when heated, as shown in the X-ray diffraction patterns of Fig. 1, as described in the present application with reference to Example 8 on page 24. Without wishing to be bound by theory, the crystalline phase produced in the present fillers may be a result of an accelerated crystal growth due to the content of CaO and/or MgO resulting from the process of forming the elongated silica particles. It is respectfully submitted that one of ordinary skill in the art would expect that the result of such a heat process, involving a temperature of 800°C in Example 8, would have been unpredictable, depending on the particular silica material involved.

The unpredictability of heat treatment of different silica materials is further evidenced by the fact that the cluster material of Zhang/Windisch, after heating, is relatively less dense and has higher surface area. Windisch states:

> The fillers of the invention are preferably not fully densified. The term "fully dense," as used herein, is descriptive of a particle that is near theoretical density, having substantially no open porosity...the fillers of the invention are often manufactured in a process that includes heat treatment. The surface area of the filler after heat treatment compared to its surface area before heat treatment is preferably quite high. The ratio of the surface area after heat treatment compared to the surface area before heat treatment is preferably greater than about 50%, more preferably greater than about 80%. [Col. 4, line 63, to col. 5, line 17.]

In contrast, the surface area and the porosity of the filler according to the present invention, after heating at either 550°C or 1100°C, as determined by BET, was found to decrease. In fact, the heated and crystallized filler was found to approach a fully densified value and to contain substantially no open porosity, quite contrary to the filler and teachings of Zhang/Windisch. Therefore, the heat treatment in Zhang/Windisch evidently does not produce the same result, contrary to the allegation in the Office Action.

In summary, therefore, Applicants respectfully submit that the rejection of the present claims is based on a misunderstanding or incomplete understanding of Zhang. First, the present invention relates to colloidal, not fumed silica. Second, the individual nanoparticles are in the form of chains, not secondary particles formed from discrete primary particles. Third, the nanoparticles are individually dispersed in the sol, not associated into secondary particles. Fourth, the chains are dispersed in the sol, not later formed during drying and/or heating. Fifth, the heating of the elongated nanoparticles in the present invention is designed to produce crystallinity in elongated silica nanoparticles, whereas the cited prior art is purposely designed to produce essentially no crystallinity in clusters of spherical particles and instead intended to remove residual organics and increase surface area. Sixth, there is no evidence that heating clusters of a different kind of material has the same result as heating the present material. In fact, there is clearly contrary evidence.

Thus, the Applicants respectfully request reconsideration and removal of the §103(a) rejection of claims 37-39 and 41-43.

Obviousness over Zhang in view of Bullock

Claims 44-46 stand rejected under 35 U.S.C. § 103(a), as allegedly obvious over Zhang in view of US 4180911 to Bullock ("Bullock"). Applicants respectfully traverse this rejection. (12/09/2008 Office Action page 3, second to last para.)

The Office Action states that Zhang teaches surface treatment of silica with a silane, as well as additional ceramic filler and opacifying oxides. The Office Action concedes that Zhang does not teach the specific silanes of claim 44. The Office Action states, however, that Bullock teaches silane treatment of a dental filler material with specifically claimed silanes, in columns 4-5, lines 64-65. (12/09/2008 Office Action page 4, paragraphs 2 and 3.)

Applicants, however, are not contending that the silane treatment of silica fillers is *per se* new. Claims 44-46 are patentable for at least the reason that they depend from claim 37. As mentioned above, claim 37 requires two limitations not taught or suggested by Zhang: (1) drying a sol of individual amorphous silica nanoparticles in the form of chains having lengths of about 5 to about 400 nanometers; and (2) heating the dried silica sol to a temperature and for a time effective to form at least one crystalline phase within the resulting silica material. Bullock, in combination with Zhang, also fails to teach or suggest these two required limitations. Indeed, Bullock specifically discloses silane treated amorphous silica and not a silane-treated silica material having at least one crystalline phase. As the combined references fail to teach or suggest all of the required claim limitations of claim 37, the references have not rendered obvious claims 44-46. Reconsideration and withdrawal of this rejection are respectfully requested.

New Claims:

New Claims 47 and 51 recite that the X-ray diffraction pattern of material formed after the drying shows a dominant amorphous curve and no crystalline peaks, and an X-ray diffraction pattern of material formed after the heating exhibits crystalline peaks, as supported at least at page 24, para. 0061-0062. New claim 48 recites that the sol that is dried comprises amorphous "elongated" silica nanoparticles "in an aqueous solution," as supported at least at page 11, lines 9-10.

New claim 49 recites that prior to drying and heating, the sol of silica nanoparticles is mixed with a microparticulate filler, as supported at least at page 12, para. 0033. New claim 50 recites that prior to drying and heating, the sol of silica nanoparticles is mixed with a microparticulate filler and an opacifying oxide or calcinable precursor thereof, as supported at least at page 14, para. 0036.

New independent claim 51 includes all the limitations of independent claim 37 and additionally requires that the sol comprises amorphous "elongated" silica nanoparticles at a temperature and for a time effective to remove liquid therefrom, wherein the silica nanoparticles comprise colloidal particles "bound to each other" in the form of chains having lengths of about 5 to about 400 nanometers, as supported at least at page 11, para. 0030.

New independent claim 52 has all the limitations of claim 37 and further requires mixing the sol with a microparticulate filler having a particle size of 0.1 to 1 micrometer, as supported at least at page 12, para. 0030. New claim 53 requires that the microparticulate filler is glass or ceramic, with specific microparticulate fillers named in claim 54 and 62, as supported at least at page 13, lines 1-9. New claim 55 requires that the heating is sufficient to form a material in which nanoparticulate silica is fused onto the microparticulate glass or ceramic surface, as supported at least at page 13, para. 0034. New claim 56 requires that the amorphous sol of silica nanoparticles and microparticulate filler are mixed by (i) preparing an aqueous or organic solution of dispersed microparticulate glass or ceramic filler under acidic or neutral conditions, and (ii) adding the sol comprising silica nanoparticles to form a gel, as also supported at least at page 13, para. 0034.

New claim 57 recites that the filler obtained in accordance with the method is a hybrid filler comprising about 40 to about 90 percent by weight of material derived from the sol of silica nanoparticles and about 1 to 20 percent by weight of the microparticulate filler, as supported at least at page 14, para. 0035. New claim 58 requires that the filler further comprises an opacifying metal oxide or calcinable precursor thereof, as supported at least at page 14, para. 00036, with specific opacifying metal oxides in claim 60. New claim 60 requires that after heating the dried mixture, the dried and heated mixture be subjected to pulverization or milling to break agglomerates, as supported at least at page 13, para. 0034. New claim 61 states that after pulverization or milling, the particles are subjected to surface silane treatment, as also supported at least at page 13, para. 0034. Finally, claims 63 and 64 claim a composition comprising the filler of claim 37 or 52, respectively, in admixture with a resin material to form a dental composite, as supported on page 15, para. 0038.

It is believed that the foregoing remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the rejections and allowance of the case are respectfully requested. The Examiner is invited to contact the attorney of record below to discuss the instant Response as a means to advance prosecution in the instant case.

If there are any additional charges with respect to this Response or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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Attachment: “Aerosil” from Wikipedia Encyclopedia, 1 page.